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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,864	04/27/2001	Martin M. Matzuk	P01925US2 (09807797)	1363

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EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/844,864

Applicant(s)
MATZUK et al.

Examiner
Cynthia B Wilder

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1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 30, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 1 and 3-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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DETAILED ACTION

1. The application has been transferred from Examiner Hope Robinson of Art Unit 1653 to Examiner Cynthia Wilder of Ar Unit 1637. All future correspondence should be directed to Examiner Cynthia Wilder whose contact information appears at the end of this Office Action.

Election/Restriction

2. Applicant's election with traverse of Group II, claim 2 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that Group I and Group II should be examined together since DNA encodes protein. Applicant contends that Group I and Group II are related as such and that this relationship does not provide an undue burden for the Examiner to perform a simultaneous search of the polynucleotide and the protein. Applicant states that in light of this argument that the Examiner has not meet the burden to establish patentably distinct inventions under MPEP 806 and 808 and respectfully request that the restriction requirement between Group I and Group II be withdrawn and that each of claims 1 and claim 2 presently pending in this application be examined.

This is not found persuasive because the invention of Group I drawn to the protein and the invention of Group II drawn to DNA are patentably distinct in structure and physicochemical properties. Because the protein of Invention I are composed of amino acids and the DNA of invention II composed of nucleotides, the inventions have different structural and functional properties. Furthermore, the compositions can be utilized in different methodologies, such that DNA is utilized in e.g. hybridization assays or amplification assays, whereas the proteins are used

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in e.g., ligand binding assays. The DNA of invention II is not required or necessary to produce the protein of invention I because proteins can be isolated directly from nature or chemically synthesized. Therefore, the different inventions of Groups I and II not only have divergent subject matter as discussed above but also requires different fields of search. The claimed inventions are deemed patentably distinct.

The requirement is still deemed proper and is therefore made FINAL. Claim 2 is pending in the instant invention. Claims 1 and 3-18 have been withdrawn from consideration as being drawn to a non-elected invention.

Specification

3. The disclosure is objected to because of the following informalities: The disclosure at pages 12, 33, 43, and 45 contain sequences that are not represented by a sequence identifier. MPEP states that all unbranched nucleotides with ten or more bases and all unbranched, non-D amino acids sequences with four or more amino acids, provided that there are at least four "specifically defined" nucleotides or amino acid, must be represented by a sequence identifier (SEQ ID NO:) and disclosed in the "Raw Sequence Listing" and computer readable format (CRF) of the sequence listing (*see MPEP 2421.02 and 2422.03*).

(b) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 10, line 10. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

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Sequence Listing

4. The computer readable form (CRF) of the sequence listing has been entered. However, non-ASCII "garbage" at the beginning and end of the files have been deleted.

Claim Rejections - 35 USC § 112: Lack of Adequate Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is drawn to an isolated polynucleotide having the polynucleotide sequence set forth in Fig. 1 (SEQ ID NO: 16). At page 8, the specification teaches that Fig. 1 is the 1276 base pair cDNA sequence of gene O1-180 (SEQ ID NO: 1). At page 13, the specification teaches that SEQ ID NO: 16 is the 976 base pair cDNA sequence of the human O1-236 gene. The specification teaches that SEQ ID NO: 16 correlates to Figure 25. Nowhere in the specification is there a teaching or disclosure wherein the sequence depicted as Figure 1 is correlated with the sequence of SEQ ID NO: 16. More specifically, the structure of the polynucleotide sequence as depicted by Figure 1 does not correlate to the structure or function of the polynucleotide sequence represented as SEQ ID NO: 16 as claimed in the instant invention. Thus the specification nor claim

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provide sufficient identifying characteristic for written description purposes. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date Applicant was in possession of the claimed invention. Absent a written description disclosing the claimed isolated polynucleotide sequence of claim 2, the specification fails to show that Applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

Claim Rejections - 35 USC § 112: Indefiniteness

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 2 is indefinite at "set forth in Fig. 1 (SEQ ID NO: 16)" because the sequence shown in Figure 1 is not identical to the sequence depicted as SEQ ID NO: 16. Additionally the sequence shown as Figure 1 is 1276 nucleotides in length whereas the sequence depicted as SEQ ID NO: 16 is only 924 nucleotides in length. The specification teaches at page 8 that Fig. 1 is the cDNA sequence of gene O1-180 and at page 13, the specification teaches that SEQ ID NO: 16 is the nucleotide sequence of human O1-236 gene. Thus, it cannot be determined the relationship of SEQ

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ID NO: 16 to the polynucleotide sequence as set forth in Fig. 1. Clarification is required as to Applicant's intent.

Prior art

9. A prior art search was performed on an isolated polynucleotide having the polynucleotide sequence of SEQ ID NO: 16. The search of the prior art did not reveal or suggest a polynucleotide sequence comprising SEQ ID NO: 16. No motivation could be found in the prior art for isolating a polynucleotide sequence comprising SEQ ID NO: 16. Accordingly an obviousness-type rejection against the claimed invention of SEQ ID NO: 16 could not be made.

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Burglin et al. (Genes Dev. Vol. 1, No. 1, pages 97-107, 1987) teach the cloning of nucleoplasmin from *Xenopus laevis* oocytes and analysis of its developmental expression. Burglin et al. teach an isolated polynucleotide sequences that is slightly similar (10.8%) to the sequence as recited in SEQ ID NO: 16 (Figure 3, page 100).

Contact Information

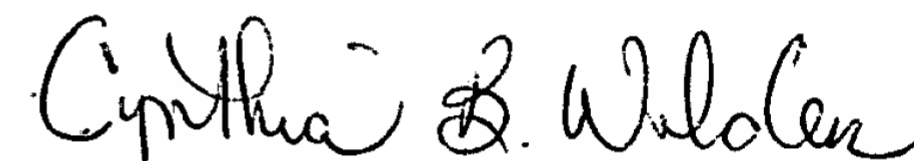
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Group's receptionist at (703) 308-0196.

cbw
February 10, 2003



Cynthia B. Wilder, Ph.D.
Patent Examiner
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